

# Underrepresentation of individuals 80 years of age and older in chronic disease clinical practice guidelines

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## Abstract

**Objective** To determine whether Canadian clinical practice guidelines (CPGs), and the evidence used to create CPGs, include individuals 80 years of age and older.

**Design** Descriptive analysis of 14 CPGs for 5 dominant chronic conditions (diabetes, hypertension, heart failure, osteoporosis, stroke) and descriptive analysis of all research-based references with human participants in the 14 guidelines.

**Main outcome measures** To identify recommendations for individuals 65 years of age and older or 80 years of age and older and for those with multiple chronic conditions.

**Results** Although 12 of 14 guidelines provided specific recommendations for individuals 65 years of age and older, only 5 provided recommendations for frail older individuals ( $\geq 80$  years). A total of 2559 studies were used as evidence to support the recommendations in the 14 CPGs; 2272 studies provided the mean age of participants, of which only 31 (1.4%) reported a mean age of 80 years of age and older.

**Conclusion** There is very low representation of individuals in advanced old age in CPGs and in the studies upon which these guidelines are based, calling into question the applicability of current chronic disease CPGs to older individuals. The variety of medical and functional issues occurring in the elderly raises the concern of whether or not evidence-based disease-specific CPGs are appropriate for such a diverse population.

## EDITOR'S KEY POINTS

- As the population ages, older individuals with chronic diseases are consuming a large portion of health care costs and services; however, clinical practice guidelines (CPGs) developed to manage these conditions are not always applicable to this population, as the studies upon which recommendations are based rarely include older participants.
- Individuals in advanced old age in particular are likely to have multiple chronic conditions; therefore, they might be the recipients of multiple evidence-based recommendations and treatments without consideration of comorbidity, conflicting management strategies, and polypharmacy.
- Most CPG recommendations are based on randomized controlled trials. Including older individuals in such research studies can be challenging owing to the high prevalence of confounding variables (greater disease severity, place of residence, comorbid conditions, functional limitation) present in this population, which can affect critical matters such as follow-up, compliance, and survival, and compromise the internal validity of the study.
- Further investigation into the applicability of research findings and recommendations to the aging population needs to be conducted, taking into account the possible interaction of multiple recommendations and medications and recognizing the mental and functional issues often present in older individuals.

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# Sous-représentation des personnes de 80 ans et plus dans les directives de pratique clinique pour les maladies chroniques

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## Résumé

**Objectif** Déterminer si les directives de pratique clinique (DPC) canadiennes et les données probantes qui servent à les créer portent aussi sur les personnes de 80 ans et plus.

**Type d'étude** Analyse descriptive de 14 DPC pour 5 conditions chroniques majeures (diabète, hypertension, insuffisance cardiaque, ostéoporose, accident vasculaire cérébral) et analyse descriptive de tout article de recherche avec des participants humains cité dans ces 14 directives.

**Principaux paramètres à l'étude** Identifier les recommandations visant les personnes de 65 ans et plus ou de 80 ans et plus, ou celles avec plusieurs affections chroniques.

**Résultats** Même si 12 des 14 directives contenaient des recommandations visant spécifiquement les sujets de 65 ans et plus, seulement 5 en contenaient pour les individus âgés de 80 ans et plus. Un total de 2559 études ont servi de preuve pour appuyer les recommandations des 14 DPC; sur les 2272 études qui mentionnaient l'âge moyen des participants, seulement 31 (1,4%) ont indiqué un âge moyen de 80 ans et plus.

**Conclusion** Les personnes très âgées sont très peu représentées dans les DPC et dans les études sur lesquelles ces directives sont basées, ce qui soulève un doute sur l'applicabilité aux personnes âgées des DPC actuelles pour les maladies chroniques. Étant donné la variabilité des problèmes médicaux et fonctionnels qui affectent les personnes âgées, on peut se demander si les DPC pour des maladies particulières fondées sur des preuves s'appliquent à une population aussi diversifiée.

## POINTS DE REPÈRE DU RÉDACTEUR

- Avec le vieillissement de la population, les personnes âgées souffrant de maladies chroniques accaparent une grande partie des coûts et services de santé; toutefois, les directives de pratique clinique (DPC) qui sont censées aider au traitement de ces conditions ne sont pas toujours applicables à cette population, puisqu'il est rare que les études sur lesquelles les recommandations sont basées portent aussi sur des sujets âgés.
- Les sujets très âgés sont particulièrement susceptibles de présenter des affections multiples; ils pourraient donc être l'objet de plusieurs recommandations et traitements fondés sur des preuves qui ne tiennent pas compte de la comorbidité, des stratégies de traitement contradictoires et de la polypharmacie.
- La plupart des recommandations des DPC sont basées sur des essais cliniques aléatoires. Il peut s'avérer difficile d'inclure des sujets âgés dans ce type d'étude en raison de la forte prévalence de facteurs parasites (maladies plus sévères, lieu de résidence, présence de comorbidité, limitations fonctionnelles) qui caractérisent cette population et qui peuvent affecter des éléments aussi importants que le suivi, l'observance thérapeutique et la survie, compromettant ainsi la validité interne de l'étude.
- L'applicabilité des résultats de la recherche et des recommandations pour la population vieillissante devra faire l'objet d'études additionnelles, compte tenu de l'interaction possible des multiples recommandations et médicaments et au vu des problèmes d'ordre cognitif et fonctionnel souvent présents chez les sujets âgés.

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With an aging population and finite health care resources, quality improvement has become a priority for health care in the 21st century. Many evidence-based clinical practice guidelines (CPGs) have been developed to promote high standards of care for chronic disease management.<sup>1-18</sup> Unlike any other age stratum, individuals in advanced old age have been found to consume a large portion of medical and care services, in part because of their higher levels of comorbidity and institutionalization.<sup>19</sup> As such, it is essential that the tools and evidence used to guide family physicians' health care practices be applicable to a senior population and, in particular, to the unique needs of individuals in advanced old age.

The World Health Organization views the increasing prevalence and incidence of chronic diseases around the world as a global epidemic.<sup>20</sup> Currently, chronic diseases account for 89% of all Canadian deaths, 80% of primary care physician visits, and two-thirds of all medical costs.<sup>21</sup> Seniors, particularly those in advanced old age (80 years of age and older), offer unique challenges to chronic disease prevention and management practices. Current studies show that more than 80% of those in this population have at least 3 chronic conditions; more than 20% have 5 or more chronic conditions; and 50% are taking 5 or more medications.<sup>22,23</sup> Despite these unique challenges, however, several recent studies highlight the exclusion of older patients from evidence-generating randomized controlled trials (RCTs).<sup>22,24,25</sup> The focus on internal validity and the restrictive admission criteria lead to the exclusion of people with more complicated medical, cognitive, and functional problems.<sup>22,24</sup> This restricts the generalizability of the studies by discounting individuals who differ substantially from the study population. If the health care needs of individuals in advanced old age are not being addressed in CPGs, and are not being considered in the evidence used to generate these CPGs, then this calls into question whether recommendations can be effectively extrapolated to guide clinicians caring for older individuals.

The purpose of this study was to analyze CPGs for 5 dominant chronic conditions (diabetes, heart failure, hypertension, osteoporosis, and stroke) to determine whether these guidelines, and the evidence used to support them, provide information for individuals in advanced old age with multiple chronic conditions.

## METHODS

### Guideline selection

Recommendations for 5 dominant chronic conditions (diabetes, heart failure, hypertension, osteoporosis, and stroke) were analyzed, specifically 14 commonly used

evidence-based chronic disease CPGs.<sup>1-18</sup> These chronic conditions were chosen because they affect a substantial percentage of older individuals, have an enormous effect on quality of life and Canadian health care costs, and have Canadian CPGs that are updated on a regular basis.

Descriptive analysis of all references published in the 14 guidelines was undertaken to determine the inclusion and representation of older individuals in the supporting evidence. The total number of references studied for each chronic disease was as follows: diabetes, N=1883; hypertension, N=299; heart failure, N=750; osteoporosis, N=600; stroke, N=163. Of these, 2559 distinct research-based studies had human participants and were used as evidence for recommendations, 2272 of which included the mean ages of the study participants.

The 2008 diabetes,<sup>1</sup> 2002 osteoporosis,<sup>14</sup> and 2006 stroke<sup>17</sup> CPGs are comprehensive peer-reviewed guidelines that were produced to replace all previously published CPGs. These were reviewed along with any associated updates. Hypertension and heart failure CPGs are updated annually, with annual updates focusing on different treatment and management areas. Therefore, the hypertension and heart failure updates from 2009, 2008, 2007, and 2006 were also reviewed.<sup>2-13</sup> All references upon which recommendations from any of the 14 CPGs were based were included, with the understanding that some references were used as evidence for multiple recommendations both within the same CPGs and across different yearly updates.

### Guideline assessment

Clinical practice guidelines were reviewed for age-specific recommendations, particularly for any identification or inclusion of frail older individuals, individuals older than 80 years of age, and individuals with multiple chronic conditions. Two sections of an instrument created by Boyd and colleagues<sup>24</sup> to assess American guidelines, and used for the assessment of Australian guidelines by Vitry and Zhang,<sup>26</sup> were adapted to assess the relevance of guidelines to the care of older people with multiple illnesses. Specifically, the "Issues Addressed" and "Recommendations" sections were expanded to distinguish between "younger" older individuals (65 to 79 years of age) and individuals in advanced old age (80 years of age or older).

### Evidence assessment

All referenced articles used as justification for clinical recommendations in the 14 CPGs (ie, those that were research-based with human participants) were extracted and analyzed to examine the extent to which older individuals were included in the evidence-generating trials. The age data are presented in 2 ways. First, they are presented as the mean age plus 1 SD. We chose to use 1 SD because in a normal distribution, 84% of study participants

**Table 1. Composite mean age distribution in the research studies used as evidence for recommendations in the clinical practice guidelines**

CLINICAL PRACTICE GUIDELINES	TOTAL NO. OF STUDIES REVIEWED	NO. OF STUDIES PROVIDING MEAN AGE*	COMPOSITE MEAN AGE, Y	NO. OF STUDIES PROVIDING SD FOR MEAN AGE	NO. OF STUDIES WITH MEAN AGE PLUS 1 SD OF $\geq 80$ Y (%)	NO. OF STUDIES WITH MEAN AGE $\geq 80$ Y (%)	NO. OF STUDIES PROVIDING AGE RANGE	NO. OF STUDIES WITH AGE RANGE CROSSING 80 Y (%)
Diabetes <sup>1</sup>	1363	1206	52.0	917	22 (2.4)	4 (0.3)	582	116 (19.9)
Heart failure <sup>2-5</sup>	500	458	68.1	356	96 (27.0)	10 (2.2)	213	116 (54.5)
Hypertension <sup>6-13</sup>	168	136	58.3	106	5 (4.7)	3 (2.2)	96	43 (44.7)
Osteoporosis <sup>14-16</sup>	473	425	64.5	354	47 (13.3)	14 (3.3)	230	118 (51.3)
Stroke <sup>17,18</sup>	55	47	61.6	28	7 (25.0)	0 (0.0)	21	18 (85.7)

\*This represents the number of studies that were included in the calculation of the composite mean age.

would be below the mean age plus 1 SD. This percentage would be even greater if the age distribution were skewed in favour of younger participants as has been reported in recent reviews.<sup>22-24</sup> It is debatable what proportion of representation a specific subgroup needs to have for the results to be applied to that subgroup, but it is conceivable that a poor outcome in the relatively small number of old people could be swamped by a positive result in the younger age group. This is particularly important if there are physiologic differences that might distinguish the smaller group from the general population, as is the case in frail older individuals.<sup>19,25</sup> Second, age range data are presented; the studies were reviewed for the age range of participants to see if the upper end of the range crossed the 80-year age threshold (Table 1<sup>1-18</sup>).

## RESULTS

### Chronic disease CPG assessment

Table 2<sup>1-18</sup> summarizes the findings from the review of the 14 CPGs included in this study. All CPGs specifically addressed individuals older than 65 years of age in their rationale and background sections. However, only the 2008 CPG for diabetes and the 2006 and 2007 CPGs for heart failure included specific sections on the prevention and management of these conditions in individuals older than 65 years of age.

Twelve CPGs provided specific recommendations for individuals older than 65 years of age. The 4 hypertension CPG updates,<sup>6-13</sup> however, all provided the same 3 recommendations, 2 of which cautioned the use of a recommended therapy (combination therapy and  $\beta$ -blockers) in elderly patients. Similarly, the only recommendation for older individuals in the 2002,<sup>14</sup> 2006,<sup>15</sup> and 2010<sup>16</sup> osteoporosis CPGs identified individuals older than 65 years of

age as being at risk of fragility fractures, suggesting that bone mineral density tests be conducted in this population. The 2008 stroke update<sup>18</sup> provided 1 recommendation on sodium intake for individuals aged 50 to 70 years and 70 years or older. Neither the 2006 stroke CPG<sup>17</sup> nor the 2008 heart failure CPG<sup>3</sup> provided recommendations specific to the 65-years-and-older age group.

With regard to frail individuals or those older than 80 years of age, 5 CPGs provided specific recommendations. All heart failure guidelines, except the 2008 update, addressed the need for frail elderly heart failure patients to be treated as a unique population.<sup>2,4,5</sup> The 2009 hypertension<sup>6,7</sup> and 2008 stroke<sup>18</sup> updates both recommended using caution in carrying out recommended therapies with frail elderly patients and acknowledged the lack of clinical trial data in this population.

### Chronic disease CPGs and multiple chronic conditions

Most of the CPGs (13 of 14<sup>1-14,16-18</sup>) discussed and provided specific recommendations for the treatment of their target conditions in the presence of at least 1 other condition, providing at least 1 specific recommendation on the issue of comorbidity. However, consideration of other comorbidities only occurred when a particular comorbidity formed part of a specific paradigm for an adverse outcome, such as when considering the management of hypertension in patients with diabetes. It was rare for guidelines to consider the effect of unrelated comorbidities, in particular multiple comorbidities or polypharmacy, on the disease management recommendations. The 2006 heart failure CPG<sup>5</sup> was the only guideline to identify the high comorbid disease burden present in frail elderly patients.

### Assessment of evidence in CPG development

Summaries of the mean ages and, where provided, SDs of the participants in the studies used as evidence in the 14 CPGs reviewed are presented in Figures 1 to 5\* and Table 1.<sup>1-18</sup>

\* To access Figures 1 to 5, go to the full-text version of this article, then click on CFPlus Additional Material on the right-hand side of the page.

**Table 2.** Review of chronic disease guidelines for the inclusion of individuals 65 years of age and older, individuals 80 years of age and older, and individuals with chronic conditions

ISSUES AND RECOMMENDATIONS	GUIDELINES													
	DIABETES <sup>1</sup>	HEART FAILURE <sup>2-5</sup>				HYPERTENSION <sup>6-13</sup>				OSTEOPOROSIS <sup>14-16</sup>			STROKE <sup>17-18</sup>	
	2008	2006	2007	2008	2009	2006	2007	2008	2009	2002	2006	2010	2006	2009
<b>Issues addressed</b>														
Treatment for patients 65 y of age or older	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Treatment for frail patients or those 80 y of age or older	No	Yes	Yes	No	Yes	No	No	No	Yes	Yes	No	No	No	Yes
Treatment for patients with 1 additional chronic disease	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Treatment for patients with multiple comorbid conditions	No	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	No
Treatment for older patients with multiple comorbid conditions	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No
<b>Recommendations</b>														
Total no. of recommendations	206	112	68	45	51	96	95	96	100	45	16	42	39	178
Specific recommendations for patients 65 y of age or older*	7	7	1	No	1	3	3	3	3	1	1	1	No	2
Specific recommendations for frail patients or those 80 y of age or older*	No	3	1	No	1	No	No	No	1	No	No	No	No	1
Specific recommendations for patients with 1 comorbid condition	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Specific recommendations for patients with multiple comorbid conditions	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No
Specific recommendations for older patients with multiple comorbid conditions	No	No	No	No	No	No	No	No	No	No	No	No	No	No

\*Presented values represent number of recommendations in the clinical practice guideline.

## DISCUSSION

There is a growing body of literature concerned with the issue that CPGs do not address the needs of older individuals with complex comorbid illnesses.<sup>25-27</sup> The findings from this review provide substantive support for these claims. Similar to the findings of Boyd

and colleagues<sup>24</sup> who reviewed 9 American CPGs, this review found that Canadian guidelines for diabetes, heart failure, hypertension, osteoporosis, and stroke offered very limited discussion and recommendations for individuals in advanced old age. Of the 2272 studies used as evidence for the recommendations in the CPGs that provided a mean age for their sample populations,




only 31 (1.4%) had a mean age of 80 years or older. Even those CPGs with sections and recommendations specific to older individuals predominately looked at the “younger” older population (ie, 65 to 79 years of age). The 2008 diabetes CPG included a specific section on diabetes in the elderly. However, only 3.4% of the studies used to justify recommendations in this section included a sample with a mean age of 80 years or older. Most of the CPGs in which frail older individuals were identified merely provided cautionary statements about applying recommendations to these patients.

Of interest is the fact that if one were to focus on the age range, where provided, one would have the impression that many studies included older subjects. However, the percentage of studies in which the mean age or 1 SD above the mean age (meaning that at least 16% of the study group was aged 80 years or older) crossed the 80-years threshold was much lower, being on average about one-fifth of the total number of studies.

Randomized controlled trials are a necessity in medical research. Including older individuals, however, particularly those in advanced old age, can be very challenging owing to the high prevalence of confounding variables (greater disease severity, place of residence, comorbid conditions, functional limitation) present in this population. These confounding factors affect such critical matters as compliance, attendance for follow-up, and even survival, and can compromise the internal validity of the studies. Funders sponsoring RCTs tend to prioritize internal validity (the degree to which the measured outcomes can be correctly attributed to the intervention) over external validity, (the extent to which the results of a study can be generalized to other populations).<sup>28</sup> Systematic reviews and guideline development, which turn the RCT results into usable recommendations, are necessarily at the mercy of the information available. Generalization of results to other populations needs to be done with caution, and it is only relatively recently that this issue has received much attention.<sup>25,29</sup>

Additionally, innovative ways to explore the value of different treatments in frail older people beyond the restrictive confines of the RCT are needed. Older individuals are likely to have multiple chronic conditions; therefore, they might be the recipients of multiple evidence-based recommendations and treatments without consideration of the effects of one set of recommendations on the other or of the effects of multiple recommendations on the patients themselves. In order to assist physicians in the management of frail older patients with multiple conditions, a hierarchical approach might be required to help physicians prioritize treatment with older individuals, initially targeting issues that are most likely to affect mortality, morbidity, and hospitalization.

## Conclusion

Evidence-based chronic disease CPGs aim to provide standards to improve the quality of care for people with chronic diseases. However, there appears to be a substantial gap between the participant population in the many evidence-based trials that are used to create recommendations in CPGs and the diverse population to whom these CPGs might be generalized. Further investigation into the applicability of research findings and recommendations for populations in advanced old age needs to be conducted. A new approach that takes into account the possible interaction of multiple recommendations and multiple medications, as well as recognizing the mental and functional issues often present in the elderly population, should be considered. 

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### Contributors

**Ms Cox** and **Drs Kloseck, Crilly, McWilliam, and Diachun** all contributed to concept and design of the study; data gathering, analysis, and interpretation; and preparing the manuscript for submission.

### Competing interests

None declared

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